UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/193,538	11/17/98	BILLING-MEDEL	P 6193.US.P1

HM12/0614

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EXAMINER	
SOUAYA, J	
ART UNIT	**PAPER NUMBER**
1655	10

DATE MAILED: 06/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/193,538	Applicant(s) Billing-Medel et al
	Examiner Jehanne Souaya	Group Art Unit 1655

☒ Responsive to communication(s) filed on *Nov 29, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-49* is/are pending in the application.

Of the above, claim(s) *23-37, 39, 40, and 42-44* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-22, 38, 41, and 45-49* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-49* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *7*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-22, 38,41, and 45-49 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The claims are drawn to polynucleotides, and methods of detecting the polynucleotides in a test sample as defined in the specification as products of a breast tissue gene designated as BS274 (pg. 10). The specification teaches the general utility for the invention is detection of the gene product itself in a sample. The specification does not teach a specific utility of the polynucleotides, genes and proteins whereby the invention would be a useful tool for a specific purpose i.e. detection of itself in a sample detects the presence of a disease. The specification also does not provide any teachings as to the function of the encoded protein. The specification suggests that the invention may have substantial utility i.e. as an anti-BS274 antibody useful as a therapeutic agent (p. 52). However, the specification does not teach the therapy or demonstrate therapeutic results. Additionally, the specification suggests that the invention may have substantial utility i.e. the gene products may be useful for the diagnosis of a breast tissue disease

or condition such as breast cancer by using the gene products to detect themselves in a tissue sample by hybridization (p. 63). However, the specification does not teach the diagnostic utility. Specifically, the specification teaches that the claimed gene products detect themselves in cancerous breast tissue. Additionally, the specification teaches that the BS274 was found in non-breast libraries (pg. 54, lines 20-25). Therefore, the specification does not teach a specific or substantial utility for the invention such that the invention would be useful to detect or treat a disease state. While the utility of gene products has been established in the art, applicants have not demonstrated a specific or substantial utility for the claimed invention.

Claim Rejections - 35 USC § 112

Enablement

3. Claims 1-22, 38, 41, and 45-49 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The specification teaches that the compositions and methods described herein will enable the identification of certain markers as indicative of a breast tissue disease or condition, and that the information obtained therefrom will aid in the detecting, diagnosing, staging, monitoring, prognosis, in vivo imaging, preventing or treating diseases of the breast, however the specification does not teach having done so. It cannot be determined from the specification what the biological function of the polypeptides

encoded by the sequences of SEQ ID NOS 1-7 nor how these polynucleotides or polypeptides are correlated to or would be useful in detecting any breast tissue diseases without undue experimentation. The teachings in the specification are an invitation to experiment.

4. Claims 1-22, 38, 41, and 45-49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the presence of a target BS274 polynucleotide consisting of SEQ ID NOS 1-7, and **the** complements of SEQ ID NOS 1-7, does not reasonably provide enablement for BS274 polynucleotides having 50% sequence identity with SEQ ID NOS 1-7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

It is well established that to claim a chemical compound, such as a polynucleotide, the inventor must be able to define the compound so as to distinguish the compound from other materials. The claimed compound must be defined in terms so as to provide a permanent and definite idea of the complete and operative invention. In the instant case, the claimed polynucleotides have not been clearly defined in terms of structure and/or function, and therefore one cannot make and use the polynucleotides as claimed. As stated in Vaek (CAFC 20 USPQ2d 1438, the "specification must teach those of skill in the art how to make and use the invention as broadly as it is claimed." However, in order to be able to make an invention, one must be able to clearly define that invention.

The claims are drawn to a method of detecting a polynucleotide having "at least 50% identity with" SEQ ID NO:s 1-7 and fragments and complements thereof (Claims 1-10) and to a gene which codes for an BS274 protein "which comprises an amino acid sequence having at least 50% identity to SEQ ID NO: 17" (Claim 45). The specification teaches a single BS274 consensus polynucleotide, SEQ ID NO: 7, the sequence of which was assembled from 5 EST clones (SEQ ID NO:1-5) and the fill-length clone (SEQ ID NO: 7) (pg. 54).

Applicant's specification discloses a single BS274 gene sequence and a single BS274 protein sequence. Yet Applicant's claims, which are to sequences having "at least 50% identity" with a few sequences taught in the specification, may encompass thousands of polynucleotides. As discussed below, Applicant's definition of "% identity" is insufficient to provide a skilled artisan with the guidance necessary to clearly define the sequences encompassed by this claim language. Without specific teachings with respect to the methods used to determine "% identity", a skilled artisan could not be expected to identify or make the polynucleotides encompassed by the instant claims. Furthermore, irrespective of how "% identity" is defined, it is clear that by any definition of "% identity", may sequences encompassed by applicant's claims, and particularly those having "at least 50% identity" with fragments of the sequences taught in the specification, would bear little resemblance to the single BS274 consensus sequence that Applicant has taught. Neither the specification nor the claims set forth any particular structural or functional characteristics that a skilled artisan could use to identify polynucleotides that constitute BS274 polynucleotides, other than those described by SEQ ID NO. The term "BS274" is not an art

recognized term, and thus the prior art is silent with respect to structural and functional features that may be used to identify such polynucleotides. Furthermore, in teaching a single BS274 polynucleotide sequence and a single BS274 protein sequence, applicant clearly has not taught the isolation of a representative number of polynucleotides that fall within the scope of the large genus encompassed by the instant claims. Thus, while the teachings of the specification and of the prior art would enable a skilled artisan to make polynucleotides consisting of SEQ ID NO: 1-7 and the complements of SEQ ID NO: 1-7, as well as polynucleotides encoding SEQ ID NO: 17, it is unpredictable as to whether a skilled artisan could make and use BS274 polynucleotides having "at least 50% identity" with SEQ ID NO: 1-7 and fragments and complements thereof, or genes encoding BS274 proteins having "at least 50% identity" with SEQ ID NO: 17. It would require undue experimentation for a skilled artisan to make and use the invention as broadly as it is claimed.

Written Description

5. Claims 1-22, 38, 41, and 45-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides wherein said polynucleotides have at least 50% identity with SEQUENCE ID NO: 1-7, and methods for using these polynucleotides to detect

themselves (Claims 1-10). The claims broadly encompass full genes, genomic sequences, all allelic variants and mutant forms for the disclosed sequences which have not been described.

The specification teaches polynucleotides consisting of SEQ ID NO; 1,-7. However the specification does not teach the function of the polypeptides encoded by the polynucleotides of SEQ ID NOS 1-7. The specification also fails to teach how these polynucleotides are involved in breast tissue diseases. There is not adequate description of the genus of polynucleotides which have at least 50% identity with SEQ ID NOS 1-7. The claims broadly encompass full genes, genomic sequences, all allelic variants and mutant forms for the disclosed sequences which have not been described. Furthermore, as it cannot be determined what is meant by polynucleotides "derived from" a BS274 polynucleotide, the claims also encompass fragments to BS274 polynucleotides. There is substantial variability among the species of nucleic acids encompassed in the scope of the claim. The specification has also not defined a structural feature of the polynucleotides which would be common to all members of the genus that constitutes a substantial portion of the genus. Also, no description of the activity of function of the encoded protein has been described. Each of the claimed inventions is a genus for which a representative number of species must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the court in *Vas Cath Inc. V. Mahurkar,* 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of species of a polynucleotide derived from a BS274 polynucleotide having

at least 50% sequence identity with SEQ ID NOS 1-7, the specification fails to show that applicant was in fact "in possession of the claimed invention" at the time the application for patent was filed.

Indefinite

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 12-22, and 45-49 are indefinite over the recitation of the phrase "derived from" in Claims 12 and 21. In the specification, applicant has defined the term "derived from" as "a polynucleotide sequences which comprises a contiguous sequence of approximately at least about 6 nucleotides....corresponding, i.e., identical or complementary to, a region of the designated nucleotide sequences" (pg. 14). Based on this definition, it is unclear as to what polynucleotides and nucleic acids would be encompassed by the language "derived from". For example, while the term "identical has a well known meaning, it is unclear as to what degree of complementarity might be encompassed by the term "complementary".

B) Claim 13 is indefinite over the recitation "hybridizes selectively". While the meaning of the term "hybridize" is well known in the art, the phrase "hybridizes selectively" could have different meaning to different people of skill in the art. As a result, it is unclear as to what extent the phrase "wherein said polynucleotide is capable of hybridizing selectively to the nucleic acid of said BS274 gene" further limits the claims.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 11-18, 45, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by the following accession numbers.

As the meaning of the term " derived from a BS274 polynucleotide" is indefinite, the term has been interpreted to meant sequences smaller than the sequences of SEQ ID NOS 1-7.

Accession number AA266770 teaches a polynucleotide which has 70% sequence identity to a portion of SEQ ID NOS 2.

Accession number A21446 teaches a polynucleotide which has 77.8% sequence identity to a portion of SEQ ID NO 3.

Accession number A43962 teaches a polynucleotide which has 74.2% sequence identity to a potion of SEQ ID NO 4.

Accession number IL691 teaches a polynucleotide which has 71.9% sequence identity to a portion of SEQ ID NO 5.

Accession number I27772 teaches a polynucleotide which has 73.5% sequence identity to a portion of SEQ ID NO 6.

Accession number I27772 teaches a polynucleotide that has 73.5% sequence identity to a portion of SEQ ID NO 7.

10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya
Patent examiner
June 9, 2000

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
6/13/00